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REMARKS

Claims 1-38 are pending in the application. Claims 1, 2 and 14-32 are under examination. Claims 3-13 and 33-38 have been withdrawn.

Claim rejections - 35 U.S.C. § 112

Claims 1-2 and 14-32 have been rejected under 35 USC § 112, first paragraph. The Examiner states that the specification and claims do not adequately describe the distinguishing features or attributes concisely shared by the members of the genus comprising oligonucleotides with non-sequence complementary mode of action and comprising random sequences, whereby prevention and treatment of HSV-2 is obtained in an organism. In order to overcome this rejection, Applicants respectfully point out that the oligonucleotides used in the present invention and claimed in claims 1-2 and 14-32 can be randomer oligonucleotides. For example, the disclosed oligonucleotide REP 2006, which contains a randomer sequence, by the nature of the preparation used to produce it, a sequence complementary mode of action cannot occur. For example, in a 15 μ mol preparation of a randomer oligonucleotide containing 31 nucleotides in length, this preparation will have at most 2 copies of every possible sequence of nucleotides. Thus, the presence of 2 copies of a specific sequence cannot account for the response observed in the present invention. In addition, it is stated in the Manual of Patent Examining Procedure that:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the genus" (Manual of Patent Examining Procedure 2163.05).

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It is thus believed that the present description discloses a sufficient and/or representative number of species. For instance, in Example 2 in the description, it is disclosed that the oligonucleotides REP 2006, REP 2055 and REP 2056 have an anti-HSV-2 activity. The distinguishing feature or attribute concisely shared by the members of the genus claimed in the present application is that the oligonucleotides have an antiviral activity occurring by a non-sequence complementary mode of action. It is believed that a person skilled in the art would recognize that this disclosure provides a representative number of species and that the Applicants were in possession of the claimed genus comprising at least 29 nucleotides in length with antiviral activity occurring principally by a non-sequence complementary mode of action, and which contain randomer oligonucleotides providing treatment and prophylactic effects against HSV-2 virus infection. In view of the arguments presented hereinabove, reconsideration and withdrawal of Examiner's rejection are earnestly solicited.

Claims 1-2 and 14-32 have been rejected under 35 USC § 112, first paragraph. The Examiner states that the present application contains subject matter which is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner further alleges that the present invention encompasses a composition or methods from the prevention and treatment of HSV-2 comprising administration of an oligonucleotide at least 29 nucleotides in length with antiviral activity occurring principally by a non-sequence complementary mode of action. Citing the references of Branch and Crooke, Peracchi *et al.*, Agrawal *et al.*, Chirila *et al.* and Opalinska *et al.*, the Examiner states that the delivery of nucleic acid *in vivo* for therapy is highly unpredictable. In order to overcome this rejection, Applicants respectfully point out that results are disclosed in the present application demonstrating the antiviral activity of the oligonucleotides claimed in the present application targeting HSV-2 virus. For instance, Example 2 and Figure 15 disclose various oligonucleotides with different lengths used to identify their efficacy as potential anti-HSV-2 molecules. In addition, it is believed that the present invention has clinical relevance and that the *in vitro* results disclosed in the present application do not diverge from the *in vivo* responses. To support this latter allegation, enclosed is a Declaration of Dr. Jean-Marc Jutcau, one of the inventors, reporting *in vivo* results obtained with *in vivo* models of the vaginal human herpes simplex-2 (HSV-2) transmission in mouse and mouse model of cytomegalovirus (CMV) infection. These *in vivo*

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models are widely accepted for testing the activity of compounds *in vivo* (see Cone *et al.*, 2006, BMC Infect. Dis., 6:90; Bernstein *et al.*, 2003, Antimicrob. Agent Chemother., 47: 3784; Scott *et al.*, 2005, J. Gen. Virol., 86: 2141 enclosed herewith). From the results reported in this Declaration, it is clear that the teaching contained in the present application is predicative of success for *in vivo* therapy. Thus, the present specification provides guidance and results which resolve the unpredictability in the art associated with *in vivo* effects provided by the claimed agents. In view of the foregoing, reconsideration and withdrawal of the Examiner's rejection of claims 1-2 and 14-32 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

It is submitted, therefore, that the claims are in condition for allowance. Reconsideration of the Examiner's rejections is respectfully requested and allowance of claims 1, 2 and 14-32 at an early date is solicited.

No additional fees are believed to be necessitated by this amendment. Should this be in error, authorization is hereby given to charge Deposit Account No. 19-5113 for any underpayment or to credit any overpayment.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully,

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Enc. Declaration of Jean-Marc Jutcau
Dr. Jean-Marc Jutcau Curriculum Vitae
Cone *et al.* Bernstein *et al.* and Scott *et al.* references